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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/110,720	07/07/1998	PATRICIA A. BILLING-MEDEL	6130.US.P1	5037

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/28/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

09/110,720

BILLING-MEDEL ET AL.

Examiner

Art Unit

Stephanie Zitomer

1634

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15-32, 34-37, 40-44 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-32, 34-37, 40-44 and 50-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

#### Application status

1. The Notice of Improper RCE mailed January 11, 2002 is withdrawn as having been in error.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 31, 2001 has been entered.
3. Rejections set forth in the previous final Office action, paper no. 20, mailed January 30, 2001, have been withdrawn in view of being mooted by cancellation of claims 11-14, 38, 39 and 49. Applicant's arguments and comments have been fully considered.
4. The rejection under 35 U.S.C. 101 for utility will not be applied to the new claims in view of reconsideration that the claimed sequences have diagnostic uses when practiced in conjunction with other tests.

#### Sequence Listing

5. The Sequence Listing, both in hard copy and CRF, is not in compliance with 37 CFR 1.823 and 1.824 in that the format is not in the form required as of July 1, 1998. A new Sequence Listing in both forms and in the newer format is required.

#### Informalities

6. The disclosure is objected to because of the following informalities:
  - (a) Figures 3A and 3B described at page 11 are not in the application and it is not clear that they have been filed.
  - (b) The use of "SEQUENCE ID NO" as a sequence designator in the specification and claims instead of "SEQ ID NO:" is improper and the disclosure thus is not in compliance with 37 CFR 1.821(d).
7. Applicant's request to hold in abeyance compliance with the foregoing objections to the disclosure is granted.

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**Objection to the specification: Lack of antecedent basis**

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant has not pointed out support in the disclosure for new claim language such as "complete complement" and "degenerate coding sequences thereof".

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

**Rejection under 35 U.S.C. 112, first paragraph: Lack of written description/New matter**

9. Claims 50-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim language which is not supported by the disclosure constitutes new matter. The new phrases in the newly presented claims that are not found in the specification are: "complete complement(s)" and "degenerate coding sequences thereof". The specification contains pages 13-22 devoted to definitions but neither phrase is found among them. "Complementary" sequences are frequently referred to in the specification but not "complete complement". On the other hand, complementary sequences of polynucleotides appear to be distinguished from shorter complementary sequences, i.e., "fragments", at page 24, lines 14-17. As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent support in the disclosure for the cited new claim language one of skill in the art would not have recognized that applicant was in possession of the claimed invention at the time of filing.

**Rejection under 35 U.S.C. 112, second paragraph: Indefiniteness**

10. Claims 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(a) Claims 50-53 are confusing in the recitation "complete complement" because it is not defined in the claim or in the specification and its meaning is therefore unclear. For example, it may denote a sequence having the same length as the cited SEQ ID NO: sequence or a sequence of any size in which each nucleotide is exactly complementary to a nucleotide of the cited SEQ ID NO: sequence. Clarification is suggested. Deletion of "complete" may be considered in view of the discussion above in paragraph 11 of the cited page 24 passage.

(b) In claim 54, "polynucleotide comprising:" and "an amino acid sequence" are *non sequitur* because it is well established in the art that a polynucleotide comprises nucleotides, amino acids. It is suggested to delete ", the isolated polynucleotide" in the second line.


#### Conclusion

11. **No claim is allowed.** However, the claims may be placed in condition for allowance by resolution of the 112, first and second paragraph issues. The Sequence Listing must be corrected before the application can be allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.



Stephanie Zitomer, Ph.D.  
March 16, 2002

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